

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

CASE NO:

NOETIC SPECIALTY INSURANCE
COMPANY,

Plaintiff,

v.

EPTAM PLASTICS, LTD. AND
GLOBUS MEDICAL, INC.

Defendants.

DECLARATORY JUDGMENT COMPLAINT

Plaintiff, NOETIC SPECIALTY INSURANCE COMPANY, sues Defendants,
EPTAM PLASTICS, LTD. and GLOBUS MEDICAL, INC. and alleges as follows:

**JURISDICTIONAL STATEMENT, IDENTIFICATION OF PARTIES,
AND GENERAL ALLEGATIONS**

1. This is an action for declaratory judgment pursuant to 28 U.S.C. sec. 2201 and 28 U.S.C. sec. 2202 for the purpose of determining an actual controversy between the parties.

2. Plaintiff, Noetic Specialty Insurance Company (“Noetic”), a Medmarc company, is a Vermont corporation, with its principal place of business in Virginia. Noetic is a citizen of the State of Vermont and the Commonwealth of Virginia for the purpose of determining diversity of citizenship.

3. Defendant, Eptam Plastics, Ltd. (“Eptam”) is and was a New Hampshire corporation with offices in Colorado and New Jersey and is conducting business in Virginia.

4. Defendant, Globus Medical, Inc. (“Globus”) is and was a Delaware corporation with offices in Pennsylvania and is conducting business in Virginia.

5. There is more than \$75,000 at issue and the parties have complete diversity. Therefore, this Court has jurisdiction under 28 U.S.C. sec. 1332 for diversity jurisdiction.

6. Noetic is located in Virginia, issued the subject Policies from Virginia, and has made the coverage decisions at issue in this action in Virginia. Venue is proper in Virginia.

7. Noetic issued Products/Completed Operations Liability Policies to Eptam Plastics, Ltd. Policy Numbers N18NH380001 and N19NH380001 (the “Policies”). Attached as Exhibit A is a true and correct copy of Policy Number N18NH380001 in effect from February 27, 2018 to February 27, 2019 (“2018 Policy”). Attached as Exhibit B is a true and correct copy of Policy Number N19NH380001 in effect from February 27, 2019 to December 1, 2019 (“2019 Policy”).

THE UNDERLYING ACTION

8. Defendant, Globus Medical is a defendant in an action in the U.S. District Court for the Middle District of Florida (“Underlying Action”) brought by Winston and Vindra Ramkelawan (“Claimants”). A true and correct copy of the Complaint is attached as Exhibit C. A true and correct copy of the Second Amended Complaint is attached as Exhibit D.

9. The Underlying Action was first filed on February 28, 2018.
10. Eptam is not a defendant to the Complaint.
11. According to the Complaint, Globus is a medical device company that designed and manufactured the SECURE-C Cervical Artificial Disc (the “SECURE-C”).
12. On May 11, 2015, Mr. Ramkelawan underwent surgery to have the SECURE-C implanted into his cervical spine.
13. The SECURE-C core allegedly expelled from between the SECURE-C endplates causing injuries to Mr. Ramkelawan’s spinal cord rendering him quadriplegic.
14. The injuries were allegedly caused by Globus’ substandard manufacture of the SECURE-C. The Complaint sounded in Strict Liability, Negligence, and Loss of Consortium by Ms. Ramkelawan.
15. The Complaint was not forwarded to Noetic, nor was any notice of a potential claim reported to Noetic at the time the Lawsuit was filed.
16. The Second Amended Complaint was filed on May 24, 2018, which in addition to the previous allegations, now alleged that the core of the SECURE-C was made of high-molecular-weight polyethylene (“UHMWPE”), and that UHMWPE is highly susceptible to oxidation causing quick deterioration.
17. It is alleged that the investigation of Ramkelawan’s SECURE-C revealed that the UHMWPE used (as received by the “Polymer Company”) was produced at least three years prior to 2011.
18. A “Machining Company” allegedly processed the UHMWPE to form the SECURE-C cores. An inspection of the subject SECURE-C allegedly revealed oxidation of the UHMWPE used to make the core.

19. Claimants allege that Mr. Ramkelawan's injuries were ultimately caused by the substandard materials and processes used to produce and manufacture the SECURE-C.

20. Notably, Mr. Ramkelawan alleges that the SECURE-C's core was delivered to Globus where it was stored for up to three years before it was packaged and labeled for distribution and sale. He further alleges that Globus sterilized the SECURE-C core, which increased the oxidation and deterioration that allegedly caused the material failure with Mr. Ramkelawan. The Counts against Globus are for Strict Liability, Negligence, and Loss of Consortium. There is no allegation of vicarious liability for Eptam's alleged manufacture of the SECURE-C core.

21. Like the original Complaint, Eptam is also not a defendant to the Second Amended Complaint.

22. The Second Amended Complaint was not forwarded or otherwise reported to Noetic upon the Eptam's receipt of same.

THE JOINT DEFENSE AGREEMENT

23. On December 12, 2018, Eptam entered into a Joint Defense and Common Interest Agreement with Globus, which states in relevant part:

WHEREAS, Winston and Vindra Ramkelawan ("Plaintiffs") commenced legal proceedings in the case styled Winston and Vindra Ramkelawan v. Globus Medical, Inc., et al., U.S. District Court (M.D. Fla.) Case No.: 5:18-cv-100-JSM-PRL (the "Litigation").

WHEREAS, The Parties share a common legal interest in the defense of the Litigation because (a) they are now named as defendants in the Litigation brought by Plaintiffs; **(b) they have not been named as defendants in the Litigation, but reasonably believe that, although this lawsuit wholly lacks merit, there is a possibility that they could be named in the**

future; (c) they have not been named as defendants in the Litigation, they are the subject of pending and expected future discovery propounded by Plaintiffs in the Litigation; and/or (d) by virtue of their role as a supplier and/or their relationship with a named defendant in the Litigation.

WHEREAS, Globus and Cozen have had communications with EPTAM and Choate in connection with the Litigation, and have entered into this Agreement, nunc pro tunc, **to document a pre-existing oral joint defense agreement previously understood and agreed to**, and to the extent it may be required to protect such previous and ongoing communications from disclosure under the joint defense and common interest privileges.

(Emphasis added).

24. Eptam knew that it could be a subject to a claim in relation to the Lawsuit, was aware of the nature of the injuries allegedly sustained by Mr. Ramkelawan (*i.e.*, quadriplegia), and that its role as the supplier was at issue in the Lawsuit.

25. The Joint Defense Agreement was not reported to Noetic at the time it was negotiated or executed.

EPTAM'S APPLICATION

26. The Insured made the following representation in its policy renewal application on February 11, 2019:

Claims/Incident Information		
51.	Have you reported to Medmarc all occurrences which may result in a claim against you in the future? Refer to your policy, Section IV. 2, Duties in the Event of Occurrence, Claim or Suit. Failure to promptly report all occurrences could result in loss of coverage.)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> If no, please explain: None

27. Neither the existence of the Underlying Action, nor the possibility of becoming a defendant to the Lawsuit was communicated to Noetic.

EPTAM'S POLICY

28. The 2019 Policy was issued based upon Eptam's application representations.

29. The Policy states the following with respect to an Insured's reporting requirements.

CLAIM AND SERIOUS ADVERSE EVENT REPORTING PROCEDURES

We are pleased your company is a Medmarc Insurance Group policyholder. Medmarc takes great pride in practicing sound liability claims-handling procedures tailored to your needs. To help you better understand when to report claims and serious adverse events to us, please review this brief summary.

Claims and Serious Adverse Events...

Serious adverse event is an undesirable experience associated with your product where the outcome to the patient is life threatening, death, required hospitalization (initial or prolonged), disability or permanent damage, a congenital anomaly or birth defect, required intervention to prevent permanent impairment or damage, or required medical intervention to prevent one of the outcomes listed in this paragraph.

Claims need to be immediately reported to Medmarc as soon as reasonably possible.

Serious Adverse Events need to be reported to Medmarc prior to the end of the policy period.

POLICY CHANGES ENDORSEMENT

D. Section 1 – Coverages, paragraph A.2. is deleted in its entirety and replaced with:

2. Notice of a Serious Adverse Event

If you receive notice during the policy period of a **Serious Adverse Event**, you must provide notice to us as soon as reasonably possible but not later than ninety (90) days after the end of the policy period. Any **Claim** arising out of a **Serious Adverse Event** shall be deemed to have been first made against the Insured at the time in which notice of the **Serious Adverse Event** was provided to us, unless the **Claim** arises out of **Serious Adverse Event** that occurred during the policy period but for which notice was first given to us within ninety (90) days after the end of the policy period, in which case the **Claim** arising out of that **Serious Adverse Event** will be deemed to have been made on the last day of the policy period in which the **Serious Adverse Event** occurred. The **Claim** must be reported to us as soon as reasonably possible.

30. The Policy has the following Insuring Agreement.

**LIFE SCIENCES
PRODUCTS/COMPLETED OPERATIONS LIABILITY
COVERAGE FORM
(DEFENSE EXPENSES ARE INCLUDED WITHIN POLICY
LIMITS)
THIS INSURANCE PROVIDES CLAIMS-MADE
COVERAGE.
PLEASE READ THE ENTIRE POLICY CAREFULLY.**

SECTION I – COVERAGES

**A. PRODUCTS/COMPLETED OPERATIONS BODILY
INJURY AND PROPERTY DAMAGE LIABILITY**

1. Insuring Agreement

a. We will pay those sums, in excess of the **Deductible**, that the **Insured** becomes legally obligated to pay as Damages because of **Bodily Injury** or **Property Damage** to which this insurance applies. This insurance only applies if:...

(4) a **Claim** because of **Bodily Injury** or **Property Damage** is first made against any **Insured** during the policy period or any **Extended Reporting Period** and is reported to us as soon as reasonably possible; and

(5) the **Claim** did not arise out of a **Serious Adverse Event** that any **Insured** knew about prior to the effective date of this policy, but did not report to us or another insurer prior to such effective date, or disclose on the Application for this insurance.

2. Notice of a Serious Adverse Event

If any **Insured** becomes aware, during the policy period, of a **Serious Adverse Event**, notice of it must be provided to us prior to the end of the policy period. Any **Claim** because of **Bodily Injury** arising out of the **Serious Adverse Event** shall be deemed to have been first made against the **Insured** at the time in which notice of the **Serious Adverse Event** was provided to us. The **Claim** must be reported to us as soon as reasonably possible.

3. Defense Expenses

a. We will have the right and duty to defend the **Insured** against any **Claim** for **Bodily Injury** or **Property Damage** to which this insurance applies and to control the defense. For any **Claim** that is not a **Suit**, the duty to defend does not require us to retain counsel.

e. In the event you are entitled by law to select independent counsel to defend you at our expense, the attorney fees and all other litigation expenses we must pay to that counsel are limited to the rates we actually pay to counsel we retain in the ordinary course of our business in defense of similar **Claims** in the community where the **Claim** is being defended.

31. The Policy contains the following exclusions:

SECTION IV – EXCLUSIONS

2. Contractual Liability

Damages for, based upon, or arising out of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for **Damages**:

- a. That the **Insured** would have in the absence of the contract or agreement; or
- b. Assumed in a contract or agreement that is an **Insured Contract**, provided the **Bodily Injury** or **Property Damage** occurs subsequent to the execution of the contract or agreement. Solely for the purposes of liability in an **Insured Contract**, reasonable attorneys' fees, and necessary litigation expenses incurred by or for a party other than the **Insured**, are

deemed to be **Damages** because of Bodily Injury or Property Damage, provided:

(1) Liability to such party for, or for the cost of that party's defense has also been assumed in the same Insured Contract; and

(2) Such attorneys' fees and litigation expenses are for defense of that party against a **Suit** in which **Bodily Injury** or **Property Damage** to which this insurance applies is alleged.

32. The Policy contains the following Responsibilities and Conditions provisions.

SECTION V – RESPONSIBILITIES AND CONDITIONS

2. Duties in the Event of a Claim

a. Notice of a Claim

You must see to it that we are notified as soon as reasonably possible of any **Claim**...

b. Assistance and Cooperation of the Insured

You and any other involved **Insured** must:

(1) Immediately send us copies of any demands, notices, summonses, or legal papers received in connection with the **Claim**...

c. Obligations at Insured's Own Costs

No **Insured** will, except at that **Insured's** own cost, voluntarily make any payment, assume any obligation, or incur any expense, other than for first aid, without out consent. This includes any amounts within the deductible.

8. Representations

By accepting this policy, you agree:

a. The statements in the Declarations, Application and **Submission Materials** are your agreements and representations and each shall be deemed to constitute a material representation made by all **Insureds**;

b. We have issued this policy in reliance upon your representations;

c. In the event of any fraud, material misrepresentation, or omission by any Insured in any application, renewal application, or Submission Materials, this policy is void as to that Insured and no coverage is afforded to that Insured...

d. This policy, together with the Declarations, Application, and **Submission Materials**, is the entire agreement between you and us.

33. The Policy contains the following definitions:

SECTION VII – DEFINITIONS

4. **Claim** means:

- a. Written notice received by any **Insured**, from any party, demanding money, services, or other compensation resulting from an **Occurrence** or stating that it is the intention of such party to hold any **Insured** responsible for an **Occurrence**; or
- b. a **Suit**.

52. **Serious Adverse Event** means an undesirable experience associated with **Your Product** where the outcome to the patient:

- a. is life threatening;
- b. is death;
- c. required hospitalization (initial or prolonged);
- d. is disability or permanent damage...

34. On August 1, 2019, Counsel for Globus indicated that the May 24, 2018 Second Amended Complaint was previously provided to Eptam, including highlights that allegedly implicate the Insured's involvement in the manufacturing process with which Claimants take issue. Those include allegations related to UHMWPE (paragraphs 26, 34, 35, 36, 38, 39, 42, 44, and 45). The key allegation is identified as paragraph 88, which involves acts that are directly attributable to the Insured's involvement in the SECURE-C manufacturing process. Earlier served Interrogatories and Requests for Production from Plaintiff directed to information in Eptam's possession were likewise forwarded to Eptam

for its assistance during discovery, sometime prior to this letter. Eptam also coordinated Globus' communications with Orthoplastic.

35. Counsel for Globus also stated that it was in receipt of materials from the Insured pursuant to the 2018 Joint Defense Agreement. Eptam did not previously report that it had hired counsel in relation to the Lawsuit and that it was providing information to assist its customer in relation to the Lawsuit even though it directly related to the Insured's involvement in the SECURE-C manufacturing process. The Supplier Agreement forwarded to Noetic is Bates stamped, which tends to show that this is one of the documents produced by the Insured in discovery in the Lawsuit of which it did not notify Noetic.

36. The Supplier Agreement between Eptam and Globus states in relevant part:

SUPPLIER AGREEMENT

3.8 Insurance Coverage. Supplier shall obtain insurance of the types and in the amounts described below with an insurance carrier that has an A.M. Best rating of A- or better.

A) Commercial General Liability and Umbrella Liability Insurance. Supplier shall maintain commercial general liability (CGL) and, if necessary, commercial umbrella insurance with combined limits of not less than \$3,000,000 each occurrence.

a. CGL insurance shall be written on ISO occurrence from CG00010196 or a substitute form providing equivalent coverage and shall cover liability arising from...liability assumed under an insured contract, including the tort liability of an another assumed in a business contract.

b. Globus shall be included as an additional insured under CGL contract using ISO additional insured endorsement CG2011 or a substitute providing equivalent coverage, and

under the commercial umbrella, for claims, or allegations of claims, arising out of the suppliers negligence, acts, or omissions in the manufacturing of products for Globus.

37. Eptam did not have Globus listed as an Additional Insured under either of its Policies with Noetic.

38. On or about August 2, 2019, Eptam first notified Noetic of the Underlying Action.

39. Noetic denied Eptam's claim on October 25, 2019.

40. On November 4, 2019, Globus first tendered its defense of the Underlying Action to Noetic.

41. Noetic denied Globus' tender on November 8, 2019.

42. All conditions precedent have been satisfied or waived.

**COUNT I
DECLARATORY ACTION REGARDING THE DEFENSE AND
INDEMNIFICATION OF EPTAM**

43. Noetic re-alleges Paragraphs 1-42 as though fully stated herein.

44. Eptam had actual knowledge of the use of its product that allegedly caused Mr. Ramkelawan to become quadriplegic and that it could become a defendant in the Underlying Action, at least as early as December 12, 2018.

45. Eptam did not report the Serious Adverse Event at issue in the Underlying Action to Noetic during the 2018 Policy.

46. Eptam did not report the Serious Adverse Event at issue in the Underlying Action to Noetic in its February 11, 2019 Policy Application. Eptam had knowledge of the Serious Adverse Event when the 2019 Policy went into effect.

47. It is Noetic's position that there is no coverage for the defense of Eptam under the 2018 Policy because Eptam did not report the claim to Noetic during the 2018 Policy's reporting period.

48. It is Noetic's position that there is no coverage for the defense of Eptam under the 2019 Policy because Eptam knew of the Serious Adverse Event at issue in the Underlying Action when the Policy went into effect and because the Serious Adverse Event was not reported in its Policy Application.

49. Additionally, Eptam has not been sued in the Underlying Action. Therefore, it is Noetic's position that the duty to defend has not been invoked under the Insuring Agreement of the 2019 Policy since there is no actual suit against Eptam for damages.

50. A genuine dispute has arisen between the parties as to the existence of coverage for the defense as against a pre-suit demand from Globus. To date, no direct claim has been made by Claimants upon Eptam.

51. In view of the foregoing and by the terms of Title 28 U.S.C. sec. 2201 et seq., this Court has the right and power to declare the rights and liabilities of the parties and to give such other and further relief as may be necessary.

WHEREFORE, Noetic seeks a declaratory judgment ruling as follows:

- A. That Noetic has no duty to defend or indemnify Eptam for the pre-suit demand by Globus; and
- B. For such further relief as the Court deems just and proper.

COUNT II
DECLARATORY ACTION
Duty to Defend and Indemnify to Globus

52. Noetic realleges Paragraphs 1-42 as though fully stated herein.

53. On November 4, 2019, Globus first tendered its defense and indemnification to Noetic after litigating the Underlying Action since approximately March 2018. Globus did not report the Underlying Action to Noetic before its November 4, 2019 communication to Noetic. As a matter of the violation of the cooperation and notice requirements under the Policies, it is Noetic's position that there is no coverage available to Globus.

54. Further, it is Noetic's position that since the Insuring Agreement is not invoked with respect to Eptam, Globus does not have coverage for the Underlying Action as an insured contract because it cannot have greater coverage than a named insured under the terms of the Policy.

55. Moreover, neither the Policy nor the Supplier Agreement require that Eptam or its insurer provide coverage for Globus' own negligence. At this time, it is only Globus' negligence that is alleged by Claimants.

56. A genuine dispute has arisen between the parties as to the existence of coverage for Globus.

57. In view of the foregoing and by the terms of Title 28 U.S.C. sec. 2201 *et seq.*, this Court has the right and power to declare the rights and liabilities of the parties and to give such other and further relief as may be necessary.

WHEREFORE, Noetic seeks a declaratory judgment ruling as follows:

- A. That Noetic has no duty to defend or indemnify Globus for the Underlying Action; and
- B. For such further relief as the Court deems just and proper.

Noetic demands trial by jury as to all issues triable as of right.

Dated: November 22, 2019

Respectfully submitted,

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